UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,004	03/31/2004	Andrew T. Beckman	END5096.0515521	1279
27777 PHILIP S. JOH	7590 12/27/200 NSON	EXAMINER		
JOHNSON & JOHNSON			TOWA, RENE T	
ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003		A	ART UNIT	PAPER NUMBER
			3736	
			MAIL DATE	DELIVERY MODE
			12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		¢ *	7			
	Application No.	Applicant(s)	T			
	10/815,004	BECKMAN ET AL.	1			
Office Action Summary	Examiner	Art Unit				
	Rene Towa	3736				
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet wi	th the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory perions for reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the mail earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNIC 1.136(a). In no event, however, may a root od will apply and will expire SIX (6) MON oute, cause the application to become AB	CATION.  eply be timely filed  THS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 19	October 2007.					
2a)⊠ This action is <b>FINAL</b> . 2b)□ Th						
3) Since this application is in condition for allow	vance except for formal matte	ers, prosecution as to the merits is				
closed in accordance with the practice under	r <i>Ex par</i> te Quayle, 1935 C.D	. 11, 453 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1,2,4,5,8,9 and 11-24</u> is/are pendin	g in the application.					
4a) Of the above claim(s) is/are withdo	• ' '					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1,2,4,5,8,9 and 11-24</u> is/are rejecte	d.					
7) Claim(s) is/are objected to.		·				
8) Claim(s)are subject to restriction and	l/or election requirement.					
Application Papers						
9) The specification is objected to by the Exami	ner.	•				
10) The drawing(s) filed on is/are: a) □ a	ccepted or b) objected to	by the Examiner.				
Applicant may not request that any objection to the	ne drawing(s) be held in abeyan	ce. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the corre	ection is required if the drawing(	s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119		·				
12) Acknowledgment is made of a claim for foreig	gn priority under 35 U.S.C. §	119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority docume	nts have been received.					
2. Certified copies of the priority docume	nts have been received in A	pplication No				
<ol><li>Copies of the certified copies of the pr</li></ol>	iority documents have been	received in this National Stage				
application from the International Bure	, , , ,					
* See the attached detailed Office action for a li	st of the certified copies not	received.				
Attachment(s)						
1) X Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)		ummary (PTO-413) )/Mail Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date		formal Patent Application (PTO-152)				

Application/Control Number: 10/815,004 Page 2

Art Unit: 3736

## **DETAILED ACTION**

1. This Office action is responsive to an amendment filed October 19, 2007. Claims 1-2, 4-5, 8-9, and 11-24 are pending. Claims 3, 6-7 and 10 are cancelled. No new claims have been added. Claims 1, 4-5, 8-9, 12-13, 15 and 18-20 are amended.

## Claim Rejections - 35 USC § 103

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. Claims 1, 8-9, 11-15 and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer (US 5,286,257) further in view Burbank et al. (US 6,662,041).

In regards to **claim 1**, Barsch disclose(s) a method of deployment of a biopsy marker at a biopsy surgical site within a body by use of a biopsy device, the method comprising:

a probe 10 defining a cutter lumen 16 having proximal and distal openings, and a marker deployment rod 52 configured to be distally advanceable and proximally retractable through the cutter lumen 16;

retracting the marker deployment rod 52 to expose the proximal opening of the cutter lumen 16;

retracting a cutter 52 to expose a cutter lumen 16 of a biopsy probe 10;
providing a biopsy marker introduction assembly comprising an introducer tube
44, a marker 42 disposed in the introducer tube 44, and a marker deployment rod 52

disposed for translation within the introducer tube 44, the marker deployment rod 52 having trailing and leading ends;

inserting the biopsy marker introduction assembly into the proximal opening of the cutter lumen 16; and

distally advancing the marker deployment rod 52 and thus the marker 42 to cause deployment at the biopsy surgical site (see fig. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to **claim 8**, Barsch disclose(s) a method, further comprising proximally extending the marker deployment rod 52 from the cutter lumen 16 wherein distally advancing the cutter 52 deploys the marker 42 as the cutter 52 approaches the cutter lumen 16 (see fig. 5; column 6/lines 58-66).

In regards to **claim 9**, Barsch disclose(s) a method, further comprising distally advancing the marker deployment rod 52 across a distal lateral opening 22 in the biopsy probe 10 enabling retraction of the biopsy probe 10 without disturbing the deployed marker 42 (see column 7/lines 7-12).

In regards to **claim 11**, Barsch disclose(s) a method, further comprising percutaneously deploying the marker 42 during a core needle biopsy procedure (see column 6/lines 35-51).

In regards to **claim 12**, Barsch disclose(s) a biopsy marker introduction device for deploying a biopsy marker 42 through a biopsy instrument having a probe 10 defining a cutter lumen 16 including a distal opening 22 and an accessible proximal

opening and a marker deployment rod 52 translatable through the cutter lumen 16, the device comprising:

an introducer tube 44 configured to be received in the cutter lumen 16 and having a distal opening 48;

a marker 42 slidingly received in the tube 44; and

a marker deployment rod 52 at least partially disposed in the introducer tube 44 proximal to the marker 42 and slidingly received in the introducer tube 44, and the marker deployment rod 52 to deploy the marker 42 through the lateral distal opening 48 (see figs. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to **claim 13**, Barsch disclose(s) a device, further comprising a proximal collar 82 attached proximally to the introducer tube 44 and configured for manipulating the device into the cutter lumen 16 (see fig. 12).

In regards to **claim 14**, Barsch disclose(s) a device, further comprising an alignment feature (76, 78, 80) configured to rotationally orient the tube 44 in the cutter lumen 16 (see column 7/lines 36-42).

In regards to **claim 15**, Barsch disclose(s) a device, further comprising a pneumatic sealing feature (i.e. tight fitness of plunger 52 to the wall of the tube 44) dynamically sealing the marker deployment rod 52 to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to **claim 19**, Barsch disclose(s) a device, wherein at least a portion of the tube 44 and marker deployment rod 52 comprise a resilient material for flexibly inserting the device into the biopsy instrument 10 (see figs. 4C & 5-6).

In regards to **claims 1 and 12**, Barsch discloses a system, as described above, teaches all the limitations of the claims except Barsch does not teach a plunger that is separable into a deployment rod and a cutter.

However, Fischer discloses an introduction device comprising a cutter 20 and a deployment rod 22; wherein the deployment rod 22 includes a cutter seat 68 proximate to the trailing end configured for abutment with a cutter 20; wherein the cutter seat 66 has a diameter greater than that of the cutter 20 (see figs. 2, 4-7; column 3/lines 1-6 & 24-68; column 4/lines 1-5).

Since Barsch discloses a plunger 52 (see fig. 4C & 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter since such a modification would amount to a design choice, which serves the same purpose of moving the marker for deployment (see fig. 6). Moreover, Applicant has not disclosed that having a plunger that is separable into a deployment rod and a cutter provides an advantage, is used for a particular purpose, or solves a stated problem. Even further yet, it has previously been held that making separable is not patentable--See *In re Dulberg, 289 F. 2d 522, 523, 129 USPQ 348, 349 (CCPA 1961)*.

Page 6

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter similar to that of Fischer in order to deploy the marker by continued movement of the cutter.

Further in regard to claims 1 and 12, Barsch as modified by Fischer discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface.

However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6).

It would have been obvious to one of ordinary skill in the art at the time

Applicant's invention was made to provide a system similar to that of Barsch as

modified by Fischer with a lateral opening with a ramped driving surface similar to that

of Burbank et al. in order to readily bias the marker out of the device.

4. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch (177) in view of Burbank et al. (1041) in view of Fischer (1257) even further in view of Lamoureux et al. (US Patent No. 6,554,760).

Barsch as modified by Fischer and Burbank et al. discloses a device, as described above, that teaches all the limitations of the claim except Barsch as modified by Burbank et al. does not teach a removable sealing tip.

However, Lamoureux et al. disclose a device comprising a removable sealing tip 32 engageable over the deployment opening (see fig. 1).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Barsch as modified by Fischer and Burbank et al. with a seal similar to that of Lamoureux et al. in order to seal the biopsy needle and keep the marker from spilling out of the needle or body fluid from entering the needle prematurely (see Lamoureux et al., column 4/lines 22-24).

5. Claims 2 & 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view Burbank et al. (US Patent No. 6,161,034).

Barsch as modified by Fischer and Burbank et al. ('041) discloses method as described above and further as follows:

In regards to **claim 2**, a method wherein a distal portion of the cutter lumen 16 communicates with a pneumatic source (see Barsch, column 1/lines 20-45).

In regards to **claims 6**, Barsch as modified by Fischer and Burbank et al. ('041) ('041) disclose(s) a method, further comprising sizing a thickness of the introducer tube 44 to enable advancing the cutter 52 into the cutter lumen 16 with the introduction assembly inserted therein, wherein distally advancing the cutter 52 comprises distally advancing the cutter 52 into the cutter lumen 16 (see Barsch, see fig. 4C & 5-6; column 6/lines 35-51 & 58-66).

Barsch as modified by Fischer and Burbank et al. ('041) discloses a method, as described above, that teaches all the limitations of the claim including except Barsch as

modified by Fischer and Burbank et al. ('041) does not teach the step of insufflating the biopsy surgical site with the pneumatic source.

However, Burbank et al. disclose a method comprising the step of insufflating the biopsy surgical site (see Burbank et al. ('034), see column 14/lines 10-17 & 24-26).

It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer and Burbank et al. ('041) with a method step similar to that of Burbank et al. in order to accommodate fluid filled markers that are detectable by ultrasound or X-ray (see Burbank et al. ('034), see column 14/lines 24-26).

6. Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view Zarins et al. (US Patent No. 6,605,047).

Barsch as modified by Fischer and Burbank et al. ('041) discloses a method, as described above, that teaches all the limitations of the claim except Barsch as modified by Fischer and Burbank et al. ('041) does not teach the step of forming a pneumatic seal between the deployment rod and the introducer tube.

However, Zarins et al. discloses a method comprising the step of forming a pneumatic seal 78 between the deployment rod 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 31; column 9/line 65 to column 10/line 13; column 10/lines 18-21).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer

and Burbank et al. ('041) with a method step similar to that of Zarins et al. in order to deploy the marker out of the marker seat (see column 10/lines 9-13).

Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a method similar to that of Barsch as modified by Fischer, Burbank et al. ('041) and Zarins et al. with a pressure-drawn deployment rod (i.e. plunger of a syringe) since such a modification would amount to a design choice.

7. Claims 20-21 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view of Miller et al. (US Patent No. 6,638,235).

In regards to **claim 20**, Basch discloses a marker introduction device comprising: a tube 44 configured to be received in the cutter lumen 16 and having a lateral distal opening.

a marker 42 slidingly received in the tube, and

a marker deployment rod 52 proximal to the marker 42 and slidingly received in the tube 44, and having a proximal extension 70 configured for abutment with the cutter 52 to deploy the marker 42 through the lateral distal opening (see figs. 4C, 5-6, & 11-12; column 1/lines 20-45; column 3/lines 7-28; column 5/lines 57-67; column 6/lines 35-51 & 58-66; column 7/lines 7-12, 17-28 & 36-42).

In regards to **claim 21**, Barsch disclose(s) a marker introduction device, wherein the marker deployment rod 52 is operably configured to dynamically seal to the tube 44 (see column 5/line 67 to column 6/line 2).

In regards to **claim 24**, Barsch disclose(s) a marker introduction device, wherein the marker deployment rod 52 is operably configured to close the distal opening 22 in the biopsy probe 10 subsequent to marker deployment (see column 7/lines 2-5).

Barsch discloses a system, as described above, teaches all the limitations of the claims except Barsch does not teach a plunger that is separable into a deployment rod and a cutter.

However, Fischer discloses an introduction device comprising a cutter 20 and a deployment rod 22; wherein the deployment rod 22 includes a cutter seat 68 proximate to the trailing end configured for abutment with a cutter 20; wherein the cutter seat 68 has a diameter greater than that of the cutter 20 (see figs. 2, 4-7; column 3/lines 1-6 & 24-68; column 4/lines 1-5).

Since Barsch discloses a plunger 52 (see fig. 4C & 6), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter since such a modification would amount to a design choice, which serves the same purpose of moving the marker for deployment (see fig. 6). Moreover, Applicant has not disclosed that having a plunger that is separable into a deployment rod and a cutter provides an advantage, is used for a particular purpose, or solves a stated problem. Even further yet, it has previously been held that making

Application/Control Number: 10/815,004

Art Unit: 3736

separable is not patentable--See *In re Dulberg, 289 F. 2d 522, 523, 129 USPQ 348, 349 (CCPA 1961).* 

Even moreover, it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch with a plunger that is separable into a deployment rod and a cutter similar to that of Fischer in order to deploy the marker by continued movement of the cutter.

Barsch as modified by Fischer discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface.

However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6).

It would have been obvious to one of ordinary skill in the art at the time.

Applicant's invention was made to provide a system similar to that of Barsch as modified by Fischer with a lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.

Moreover, Barsch discloses a system, as described above, that teaches all the limitations of the claim including a deployment rod that distally terminates in a lateral opening with a ramped driving surface (see fig. 4C) except Barsch does not teach a distal opening including a ramped surface. However, Burbank et al. ('041) disclose a device comprising lateral opening with a ramped driving surface (see fig. 6). It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was

made to provide a system similar to that of Barsch with lateral opening with a ramped driving surface similar to that of Burbank et al. in order to readily bias the marker out of the device.

Although Basch as modified by Fisher and Burbank ('041) teaches the use of a biopsy system (see fig. 4B), Basch as modified by Fisher and Burbank ('041) does not explicitly disclose the features of the biopsy probe.

However, Miller et al. discloses a biopsy probe as follows:

In regards to **claim 20**, Miller et al. disclose(s) a core biopsy probe 10 including a cutter lumen (27, 34) that communicates between a distal opening 25 and an accessible proximal opening 100;

a biopsy handle 12 having an actuator 22 for cutting the biopsy sample through the biopsy probe 10 (see figs. 1-2; column 7/lines 4-6 & 21-23; column 8/lines 49-50 & 61-64; column 45-48).

Even moreover yet, It would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a device similar to that of Basch as modified by Fisher and Burbank ('041) with a biopsy probe similar to that of Miller et al. in order to mark the biopsy site without retracting the biopsy probe and thus maintaining the percutaneous site (i.e. similar in function to an introducer sheath) (see Barsch, fig. 4B).

8. Claims 22-23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barsch ('177) in view of Fischer ('257) further in view of Burbank et al. ('041) even further in view of Miller et al. et al. ('235) even further yet in view of Zarins et al. ('047).

Application/Control Number: 10/815,004 Page 13

Art Unit: 3736

Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. discloses a system, as described above, that teaches all the limitations of the claim except Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. does not system with a pressure-drawn deployment rod that is capable of insufflating a surgical site.

However, Zarins et al. discloses a system comprising a pneumatic seal 78 between the deployment rod 30 and the introducer tube 58 wherein distally advancing the cutter 30 forms a syringe pressure proximally to the pneumatic seal 78 (see fig. 31; column 9/line 65 to column 10/line 13; column 10/lines 18-21).

It would have been obvious to one of ordinary skill in the art the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. as further modified by Miller et al. with an actuation system similar to that of Zarins et al. in order to deploy the marker out of the marker seat (see column 10/lines 9-13).

Moreover, since Zarins et al. further discloses replacing the plunger altogether with a fluid actuation system (i.e. a syringe) (see column 10/lines 22-25), it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide a system similar to that of Barsch as modified by Fisher, Burbank et al. ('041) and Miller et al. et al. as further modified by Zarins et al. with a pressure-drawn deployment rod (i.e. similar to a vacuum-actuated syringe plunger) that is capable of insufflating the surgical site since such a modification would amount to a design choice.

## Response to Arguments

9. Applicant's arguments filed October 19, 2007 have been fully considered but they are not persuasive. Applicant argues that Barsch and Fisher fail to teach a cutter. This argument has been considered but has not been deemed persuasive.

In regards to the Applicant's argument, the Examiner respectfully traverses. First, the Examiner notes that this argument has already been addressed in the Advisory Action dated January 16, 2007 wherein the Examiner pointed out the Applicant that the term "cutter" in and by itself in the claim does not provide sufficient structure to distinguish over the prior art as disclosed in the last Office action. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a cutter that cuts or is adapted to cut through tissues and/or markers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Second, the Examiner notes that nowhere in the language of the claims is there a recitation of a cutter that cuts through anything. For example, claim 1 requires:

a cutter configured to be distally advanceable and proximally retractable through the cutter lumen (see lines 5-6):

retracting the cutter to expose the proximal opening of the cutter lumen (see line 7); bringing the cutter and the cutter seat portion of the marker deployment rod into abutment (see line 15); and,

distally advancing the cutter to drive the marker deployment rod and thus the marker to cause deployment of the marker through the distal opening of the cutter lumen at the biopsy surgical site (see lines 17-19).

Essentially, from the language of the claim, it is clear that a "cutter" is a structure that is "configured to be distally advanceable and proximally retractable through the

Page 15

Art Unit: 3736

cutter <u>lumen</u>" such that <u>"retracting the cutter"</u> exposes <u>"the proximal opening of the</u> cutter lumen" and "bringing the cutter and the cutter seat portion of the marker deployment rod into abutment" achieves an arrangement such that "distally advancing the cutter" drives "the marker deployment rod and thus the marker to cause deployment of the marker through the distal opening of the cutter lumen at the biopsy surgical site." The Examiner's Office action fully establishes that the prior art combination, as explained supra, provides a structure that is "configured to be distally advanceable and proximally retractable through the cutter lumen" such that "retracting the cutter" exposes "the proximal opening of the cutter lumen" and "bringing the cutter and the cutter seat portion of the marker deployment rod into abutment" achieves an arrangement such that "distally advancing the cutter" drives "the marker deployment rod and thus the marker to cause deployment of the marker through the distal opening of the cutter lumen at the biopsy surgical site." Applicant's intentional refusal to add limitations clarifying that the cutter cuts or is capable of cutting through tissues or markers is in and by itself an inference that the instant claims are broader than what Applicant actually argues. As such, one should not erroneously assume that the cutter as described in the claim has to cut through tissues or markers as previously argued by Applicant simply because the claims do not say it [the cutter] does. Moreover, the fact that the method steps, as explained above, can be carried out using any structure other than one that necessarily cuts through tissues and markers, is more of a testament to just how broad the claims are but also an indication that the method is at least obvious over the prior combination and fails to provide any step that has not been met by the instant Office

action. Rather, Applicant's arguments are solely hung on a term "a cutter," which Applicant believes is sufficient to imply that it should cut through tissues or markers absent any specific step in the claims articulating that function or attribute of the claimed method. Even moreover, it may be possible that the plunger 52 of Barsch be capable of cutting through soft tissues such as lung or brain tissues by the mere fact that Barsch states that the plunger may be "a rigid rod" with "an axially inclined surface" (see col. 5, lines 62-67). Even moreover yet, US 6,436,068 to Bardy discloses an embodiment comprising a plunger assembly 20 that includes a cutter 29 abutting a rod 17 for a subcutaneous marker deployment system (see figs. 3 & 4A).

In view of the foregoing, the rejections over Barsch and Fisher are maintained.

## Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Mafficendery

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rene Towa whose telephone number is (571) 272-8758. The examiner can normally be reached on M-F, 8:00-16:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/RTT/